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Paper 65

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

PAUL KHAVARI
and HONGRAN FAN
(6,087,341),
Junior Party,

v.

DE-CHU TANG,
DONALD H. MARKS, DAVID T. CURIEL, and ZHONGKAI SHI
(09/402,527),
Senior Party.

MAILED

SEP 17 2012

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Interference No. 104,696

Before SCHAFER, TORCZON, and NAGUMO, Administrative Patent Judges.

TORCZON, Administrative Patent Judge.

JUDGMENT
(PURSUANT TO 37 CFR § 1.662)

INTRODUCTION

Both parties have moved for judgment that there is no interference-in-fact. Khavari has contingently requested adverse judgment in the event of a decision that an interference-in-fact exists and has indicated its willingness to have the patentability issues it has raised about Tang's claims be considered in ex parte prosecution. Tang has a motion to change the count and five unpatentability motions. Tang would like its other motions decided.

INTERFERENCE-IN-FACT

- [1] Khavari moved for judgment that no interference-in-fact existed (Paper 24). The motion was denied in an interlocutory decision of a single administrative patent judge (Paper 28). Khavari has requested reconsideration (Paper 35). Tang opposes the request for reconsideration (Paper 54).
- [2] Tang has also requested judgment of no interference-in-fact (Paper 42).
- [3] Count 1, the sole count, is:

The method of Khavari claim 1 or of Tang claim 167.

- [4] Khavari claim 1 is:

A method for inducing an immune response in a vertebrate, the method comprising the steps of:

- applying topically to skin of a subject an immunogen-encoding polynucleotide in an amount sufficient for uptake by a skin cell and sufficient for expression of the immunogen-encoding polynucleotide and induction of an immune response, wherein the skin to which the polynucleotide is applied comprises hair and is not treated with a chemical or mechanical irritant, and wherein the polynucleotide is operably linked to a promoter, and is not contained within a viral particle.

- [5] Tang claim 167 is:

A method of non-invasively inducing a protective systemic immune response, comprising topically administering, a DNA vector that encodes a gene of interest and expresses a protein encoded by the gene of interest, to the skin of a mammal, in an effective amount to induce said protective systemic immune response to said protein, wherein a systemic immune response to said protein is induced in said mammal; and, whereby said protein comprises an antigen or immunogenic fragment thereof.

- [6] Khavari argues (Paper 24 at 3) that its claim 1 requires that "the skin to which the polynucleotide is applied comprises hair and is not treated with a chemical or mechanical

irritant", while Tang claim 167 requires no comparable limitations. According to Khavari (Paper 24 at 7), its claim 1 defines, at most, a species of the Tang claim 167.

[7] Mammals are vertebrates [1002 at 1].

[8] Hair is characteristic of mammalian skin, although not all mammalian skin has hair [1002 at 2].

[9] Khavari's disclosure states [2001 at 4:17-20]:

Preferably...the skin to which the polynucleotide is applied is intact and is not pretreated to remove hair.

[10] Khavari submitted portions of Tang's disclosure [2002]:

[10.1] The first page provides part of a protocol involving shaving and chemically depilating mice. The protocol also includes the use of adenovirus as a vector.

[10.2] The second page describes evidence that "shaving appeared as an essential component for NIVS [non-invasive vaccination onto the skin] presumably due to the mechanical removal of cornified epithelium along the shaving path." The example involved "adenovirus-mediated NIVS".

[10.3] The third page provides an example involving pre-shaved mice. Again an adenovirus vector [AdCMV] is used.

[11] It is not clear whether any of these examples involve a "immunogen-encoding polynucleotide...not contained within a viral particle" as required in Khavari claim 1.

[12] Tang's involved claims 148 and 149 state:

148. A method of non-invasively inducing a systemic immune response, comprising topically administering, a plasmid DNA and liposome complex vector that encodes a gene of interest and expresses a protein encoded by the gene of

interest, to the skin of a mammal, in an effective amount to induce said systemic immune response to said protein, whereby a systemic immune response to said protein is induced in said mammal.

149. The method of claim 148, wherein said mammal is shaved at the site of the topical administration.

- [13] Khavari also provided portions of a Tang declaration [2005] that explains how portions of the specification support vaccination without any pretreatment of the skin. It further states by "shaving" the specification really means "clipping" or "trimming" and that shaving is intended at least in part to facilitate attachment of a patch covering the vaccine.
- [14] Tang argues (Paper 42) that claim 167 requires a non-invasive procedure, but that Khavari's claim 1 does not exclude invasive procedures. Khavari's exclusion of chemical or mechanical irritants strongly suggests a non-invasive procedure. Indeed, Tang's examples of scarification and wounding (at 5) sound very much like mechanical irritation.
- [15] Khavari claim 1 and Tang claim 167 each appear on the record of this interference to require intact skin.
- [16] Tang also argues (Paper 42) that the claims comprising the count are directed to different inventions because Khavari claim 1 is directed to "an immunogen-encoding polynucleotide in an amount...sufficient for expression of the immunogen-encoding polynucleotide and induction of an immune response", whereas Tang claim 167 requires "a DNA vector that encodes a gene of interest and expresses a protein encoded by the gene of interest...in an effective amount to induce [a] protective systemic immune response to said protein". According to Tang (Paper 42 at 2-3), "protective systemic immune response" means "vaccination". No exhibit is cited for this fact.

[17] Khavari's specification contemplates vaccination [2001 at 21:63-25:53]. The "immune response" is described as conferring immunity to a host of pathogens, including pathogens that target systems other than the skin [2001 at 22:42-23:12].

Test, burden of proof, and focus

"No interference-in-fact" means that there is no interfering subject matter, that one party's claim are no impediment to a patent for the other party's claims. The movant has the burden to prove that the other party claims a different invention from its own. Case v. CPC Int'l, Inc., 730 F.2d 745, 750, 221 USPQ 196, 200 (Fed. Cir. 1984); accord Nitz v. Ehrenreich, 537 F.2d 539, 190 USPQ 413 (CCPA 1976).¹ Since the movant has the burden of proof, we focus on the limitations that the motion highlights as showing a difference. Cf. Gechter v. Davidson, 116 F.3d 1454, 1460, 43 USPQ2d 1030, 1035 (Fed. Cir. 1997) (focusing on contested limitations).

Khavari's motion

Khavari has focused on differences in the skin involved in the respective claims. Specifically, Khavari has focused on (1) the presence of hair on the skin and (2) the absence of chemical or mechanical irritants. Tang's claim does not recite either of these limitations. Assuming these limitations are the only differences, their absence, as Khavari suggests, indicate that invention claimed in Khavari's claim 1 is a species of the more general invention claimed in Tang's claim 167. A species anticipates its genus. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d

¹ Khavari cites Winter v. Fujita, 53 USPQ2d 1234 (BPAI 2000) and "Standard for Declaring a Patent Interference", 65 Fed. Reg. 79,809 (USPTO 2000) as requiring a two-way test for showing the existence of an interference-in-fact. Since Khavari (and Tang) are trying to establish no interference-in-fact, it is sufficient to show one-way distinctiveness. Aelony v. Armi, 547 F.2d 566, 570, 192 USPQ 486, 490 (CCPA 1977); Nitz, 537 F.2d at 543, 190 USPQ at 416-17.

955, 971, 58 USPQ2d 1869, 1880 (Fed. Cir. 2001). Consequently, Khavari's invention is the same as Tang's viewed in this "way" (i.e., from Khavari's claim to Tang's). The contested question is the other "way", that is, whether Tang's claim 167 would, assuming its subject matter were prior art, have anticipated or rendered obvious the subject matter of Khavari's claim 1.

A large genus does not ordinarily anticipate a species, but a small genus might anticipate even unnamed species. Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1380, 58 USPQ2d 1508, 1517 (Fed. Cir. 2001). The differences Khavari has identified are the presence of hair and the absence of chemical or mechanical irritant. Tang's claim 167 is directed to use on the skin of a mammal without further restriction regarding the skin. Khavari claim 1 is restricted to use on the skin of a vertebrate where the skin has hair. Hair is a defining characteristic of mammalian skin, although not all mammalian skin has hair. Tang's claim 167 restriction to mammals thus meets the "vertebrate" requirement of Khavari's claim 1 and provides the small genus of treating either hirsute or hairless skin.

Khavari notes several points in Tang's specification that indicate the skin has been shaved.² Assuming these examples are representative of Tang's entire disclosure, they at most indicate that Tang has a claim encompassing subject matter not expressly disclosed in its specification. Assuming that to be true, Khavari's remedy would have been to file a motion alleging a violation of 35 U.S.C. 112.³ It might well be true that if Tang's claims were limited to

² Note that Tang's involved, independent claim 148, which has a parallel requirement for mammalian skin, is further limited in claim 149 to require shaving at the administration site. By implication (and law, 35 U.S.C. 112[4]), claim 149 indicates that shaving is not a necessary part of the invention.

³ As Khavari acknowledges, it was expressly advised that a motion for no interference-in-fact is not the place to attack the patentability of the other party's claims (Paper 24 at 7). Lack of written description for a provoker's interfering claim, like no interference-in-fact and a bar under 35 U.S.C. 135(b), can be a threshold issue, but it must be properly

its disclosed invention then there would not be interfering subject matter.⁴ It is the claims as they are, however, not the specification, that we must consider in determining the existence of an interference. In construing the claim, we may not interpolate limitations from the specification absent some showing that one skilled in the art would understand the claim to include those limitations. Indeed, the Board must give claims their broadest reasonable construction.

Khavari's showing falls short of justifying the interpolation of additional limitations. Assuming Tang's claim 167 is supported for its full scope it teaches the application of a DNA vector to mammalian skin without restriction. One skilled in the art would understand that teaching to cover skin both with and without hair.

The contested lack of a pretreatment limitation (absence of chemical or mechanical irritant) presents a similar problem. Since Tang claim 167 does not mention pretreatment, its plain meaning is that no pretreatment need be used, although pretreatment is not explicitly excluded. Khavari suggests that we interpolate a pretreatment requirement from the specification, but Khavari's showing does not justify that interpolation, particularly in view of the Tang declaration [2005].

Khavari offers an analogy in the request for reconsideration (Paper 35 at 4-5): early package labeling for the analgesic acetaminophen lacked a warning about using acetaminophen with alcohol, although subsequently the warning was added. Khavari urges that the first warning

raised by motion under 37 C.F.R. § 1.633(a). (Tang did not expressly provoke this interference.) Khavari has filed a motion attacking the written description for Tang's claims (Paper 33), but no longer asks for that motion to be decided in the interference.

⁴ A prerequisite for the declaration of the interference is an examiner's having allowed at least one involved claim. 37 C.F.R. §1.606.

was generic (in the sense that it permitted use with or without alcohol) to the second warning. While Khavari's point is literally true, it does not follow that the second label was novel or unobvious. Indeed, had an applicant attempted to patent the method of administering acetaminophen without alcohol the claim would have undoubtedly been rejected over the earlier label as an anticipated or obvious from the earlier label. The burden of going forward would have then shifted to the applicant to show that either alcohol co-administration was an inherent element of the earlier label or that non-administration of alcohol produced an unexpected result. Similarly, in the present case, Tang's claim 167 on its face does not require the elements that Khavari has excluded by limitation.⁵ Thus, on its face, Tang claim 167 describes the same invention unless Khavari makes a showing of an inherent difference or shows unexpected results. As explained in the original decision denying Khavari's motion (Paper 28 at 3), a motion for judgment that there is no interference-in-fact is not a vehicle for contesting the patentability of Tang's claims, hence Khavari had to make its showing without attacking the support for the claims. It failed to do so here.

Since Khavari claim 1 and Tang claim 167 appear to define the same invention, we need not reach the question of whether the other claims provide a basis for an interference.

Tang's motion

Tang has also moved for no interference-in-fact. Tang first argues that the claims comprising the count are different because its claim 167 excludes invasive procedures, while Khavari claim 1 does not. Tang suggests (Paper 42 at 5) that one skilled in the art would

⁵ Although so-called negative limitations are no longer automatically considered indefinite, this case shows their limitations in overcoming prior art.

understand Khavari's claim to embrace scarification and wounding. It is not clear how this argument accounts for Khavari's express exclusion of chemical or mechanical irritants.⁶ Indeed, Khavari's preferred embodiment requires intact skin. Cf. Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1477, 45 USPQ2d 1498, 1501 (Fed. Cir. 1998) (noting that a claim construction that excludes the preferred embodiment is suspect). This proceeding presents the curiosity of each party arguing that a difference exists because its claim requires intact skin, but the opponent's claim does not. We find that Tang claim 167 and Khavari claim 1 both teach use of the method on intact skin.

Tang also argues that Khavari claim 1 does not teach a protective systemic immune response. According to Tang's motion a protective systemic immune response is a vaccination. Khavari explicitly teaches that its method contemplates vaccination.

Again, since Tang claim 167 and Khavari claim 1 appear to interfere, we need not reach the question of whether the other claims also provide a basis for an interference.

Conclusion

Although both parties have moved for judgment of no interference-in-fact, their arguments are mutually contradictory and ultimately unpersuasive. The Board, on behalf of the Director, remains of the opinion that the subject matter of Khavari claim 1 and Tang claim 167 interfere.

⁶ Tang casually refers to its other motions but does not explain their relevance with anything approaching specificity (at 5). Incorporation of arguments from other papers is expressly prohibited in the Standing Order (Paper 2, §13). In any case, as previously explained, a motion for no interference-in-fact is not the place for unpatentability arguments. The analysis proceeds on the basis of what the claims are, not what the movant thinks they should be.

REMAINING MOTIONS

Khavari has indicated that it is no longer interested in pursuing the interference beyond reconsideration of its motion for no interference-in-fact. Tang wants his other motions decided, but Khavari's concession moots them. Since Tang is an applicant, the examiner may consider the questions raised in Khavari's remaining motions during further prosecution.⁷

ORDER

Upon consideration of the parties' motion for judgment of no interference-in-fact, Khavari's request for reconsideration, and the cited portions of the record of this interference, it is:

ORDERED that Khavari's request for reconsideration of the denial of Khavari preliminary motion 1 be GRANTED to the extent that the denial has been reconsidered, but otherwise DENIED;

FURTHER ORDERED that Tang preliminary motion 7 be DENIED;

FURTHER ORDERED that the remaining motions of the parties be DENIED as moot;

FURTHER ORDERED that judgment on priority as to Count 1 is awarded against junior party Khavari;

FURTHER ORDERED that Khavari is not entitled to a patent containing claims 1-15 of Khavari's 6,087,341 patent, which correspond to Count 1;


FURTHER ORDERED that the preliminary statements be returned unopened;

⁷ Since the proceeding halted before Khavari filed the exhibits supporting its unpatentability motions, Tang may need to assist the examiner by providing copies of the relevant exhibits served on Tang.

FURTHER ORDERED that a copy of this decision be given a paper number and be entered in the administrative record of Khavari's 6,087,341 patent and Tang's 09/402,527 application;

FURTHER ORDERED that a copy of Khavari preliminary motions 2 and 3, as well as Tang's respective oppositions, be made of record in Tang's 09/402,527 application; and

RECOMMENDED, pursuant to 37 C.F.R. § 1.659(c), that the examiner consider the allegations of unpatentability in Khavari preliminary motions 2 and 3.


RICHARD E. SCHAFER
Administrative Patent Judge

RICHARD TORCZON
Administrative Patent Judge


MARK NAGUMO
Administrative Patent Judge

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INTERFERENCE
TRIAL SECTION

Interference No. 104,696
Khavari v. Tang

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